

# Patent Protection – A Key to Commercializing Personalized Medicine

R. Brian McCaslin, M.S., J.D.



# Outline of Patent Workshop

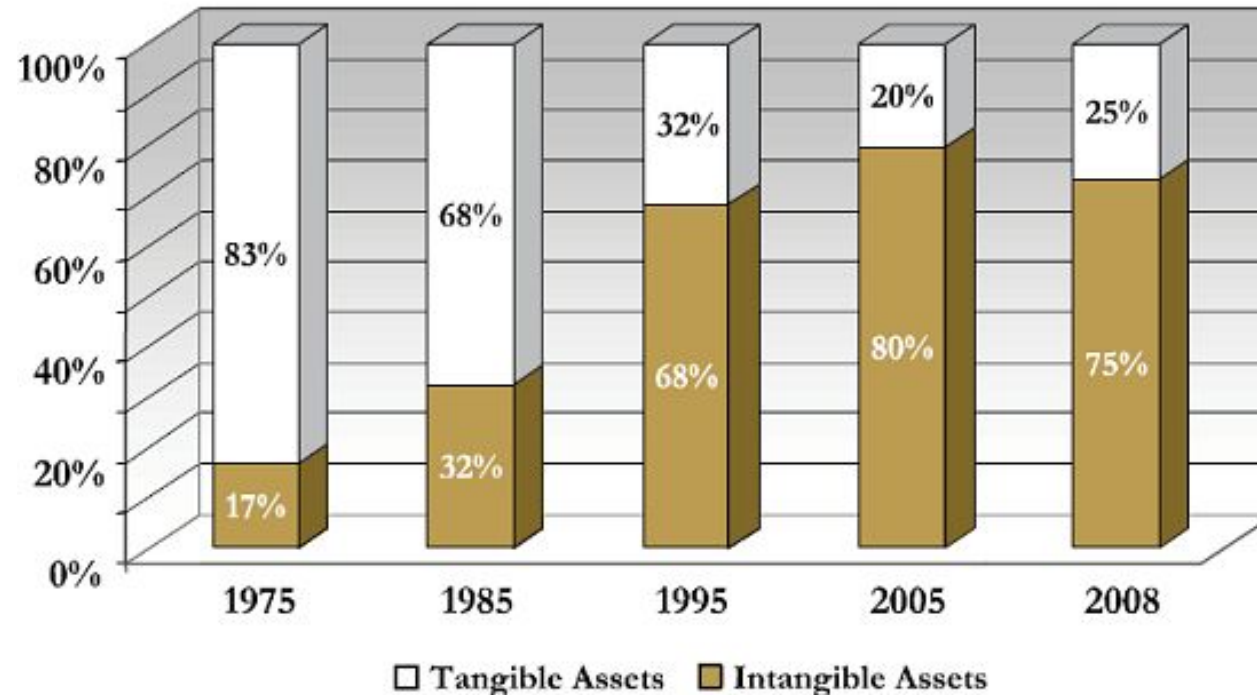
- What's the big deal?
- What is a patent?
- How do I get one?
- Recent cases impacting personalized medicine
- Proposed strategies

# Intellectual Property

- Collectively, intellectual property is considered to be “the most important set of assets for today’s emerging company.”
  - ABA, *Emerging Companies Guide*, 2005
- Intellectual property, although intangible, holds many of the same rights as tangible property.
- Intellectual property includes patents, trademarks, service marks, trade names, copyrights and trade secrets.

# Growth of Intangible Assets As a Portion of Corporate Market Cap

Components of S&P 500 Market Value



Source: Ocean Tomo

# Role of Patents

- Exclude Competitors
- Licensing
- Create assets that can be bought and sold

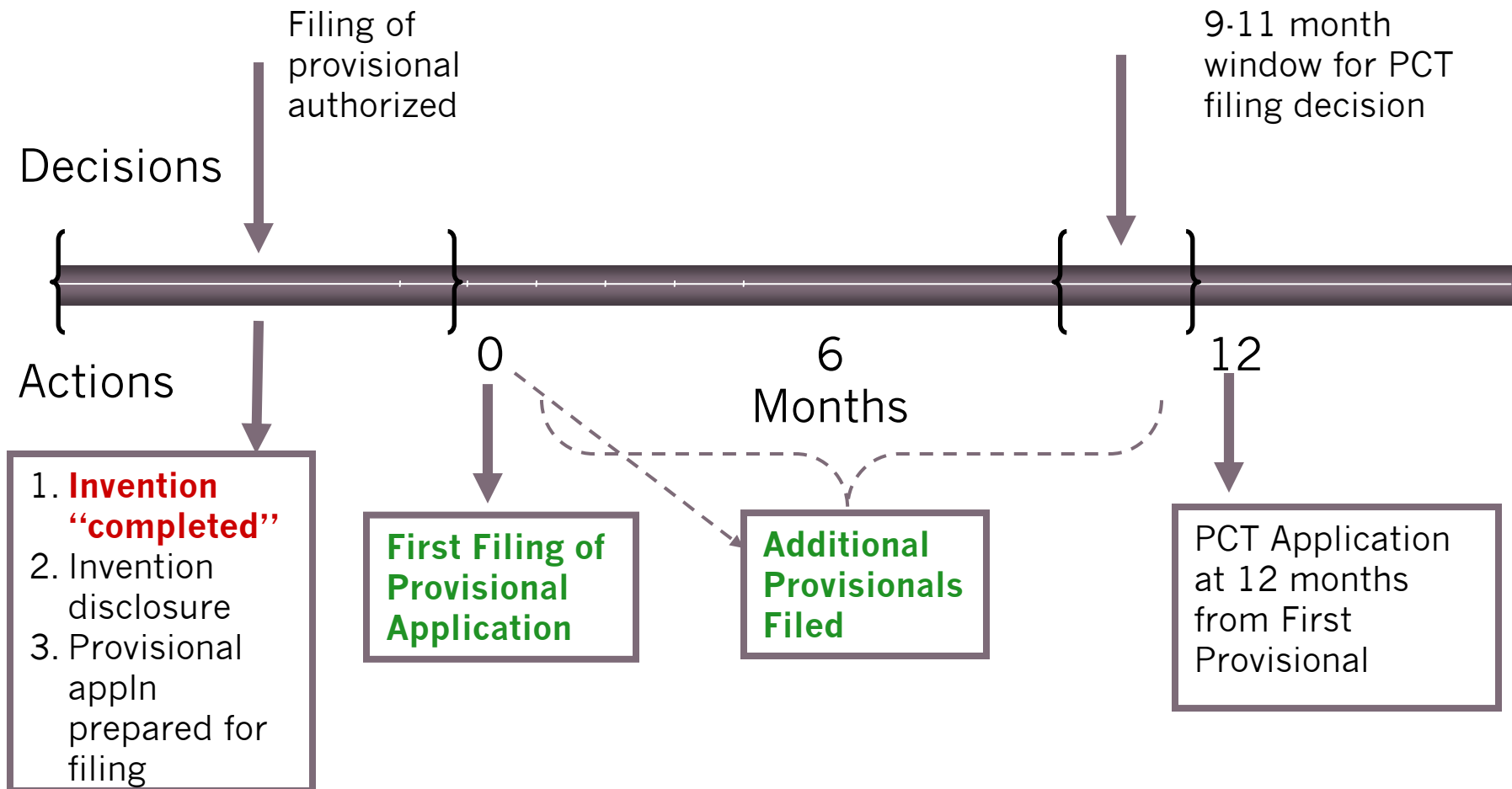
# A Patent:

- provides the grantee with a right to *exclude*,
- is *limited* in time (term) and scope (claims),
- is limited to the *granting country*, and
- can be bought /sold or licensed.

# International Patent Basics

- Each country has its own patent laws.
- Patent Cooperation Treaty has made filing in multiple countries more manageable.

# Possible International Filing Paradigm





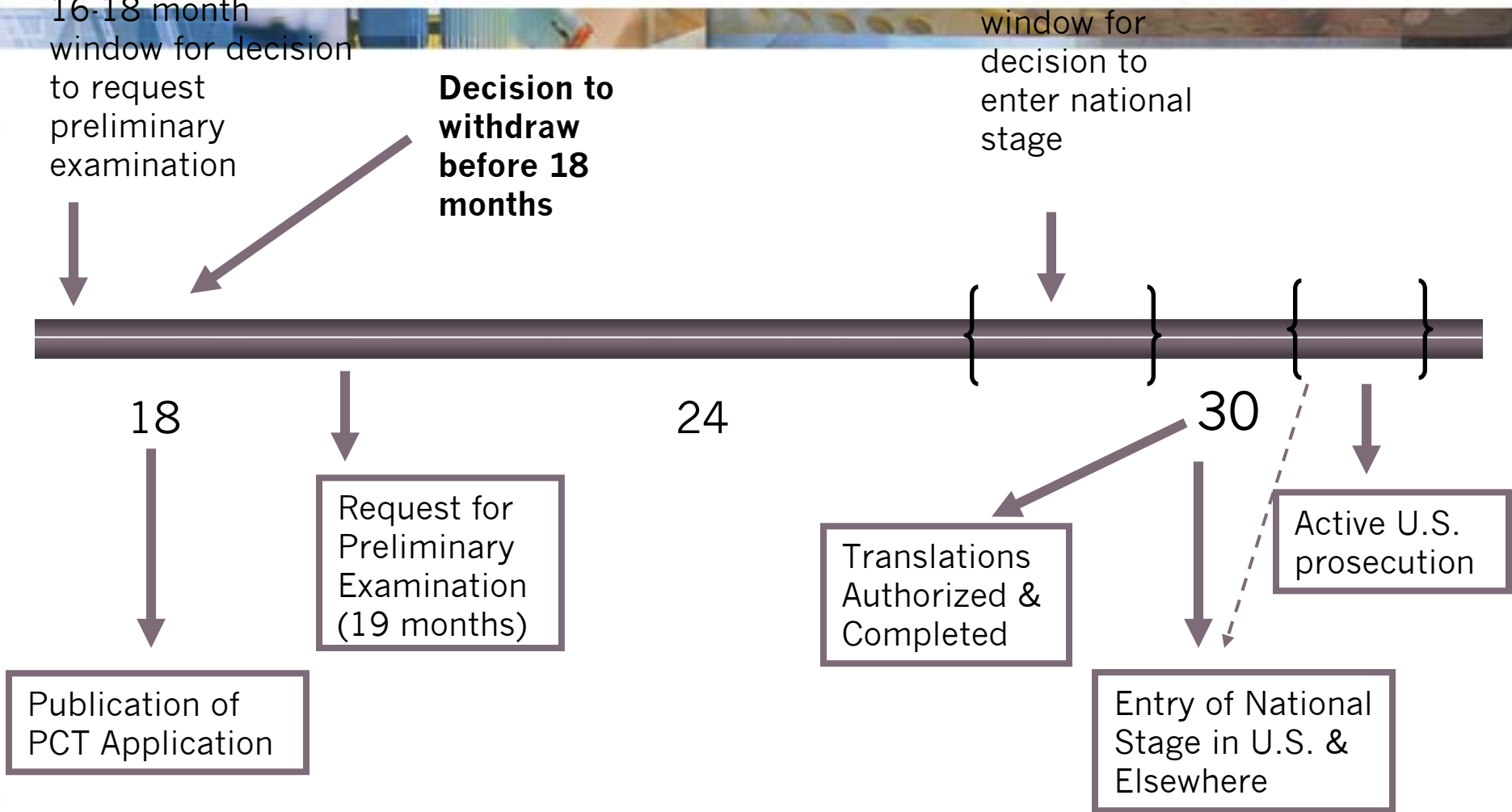
# Possible International Filing Paradigm

## Decisions

16-18 month window for decision to request preliminary examination

**Decision to withdraw before 18 months**

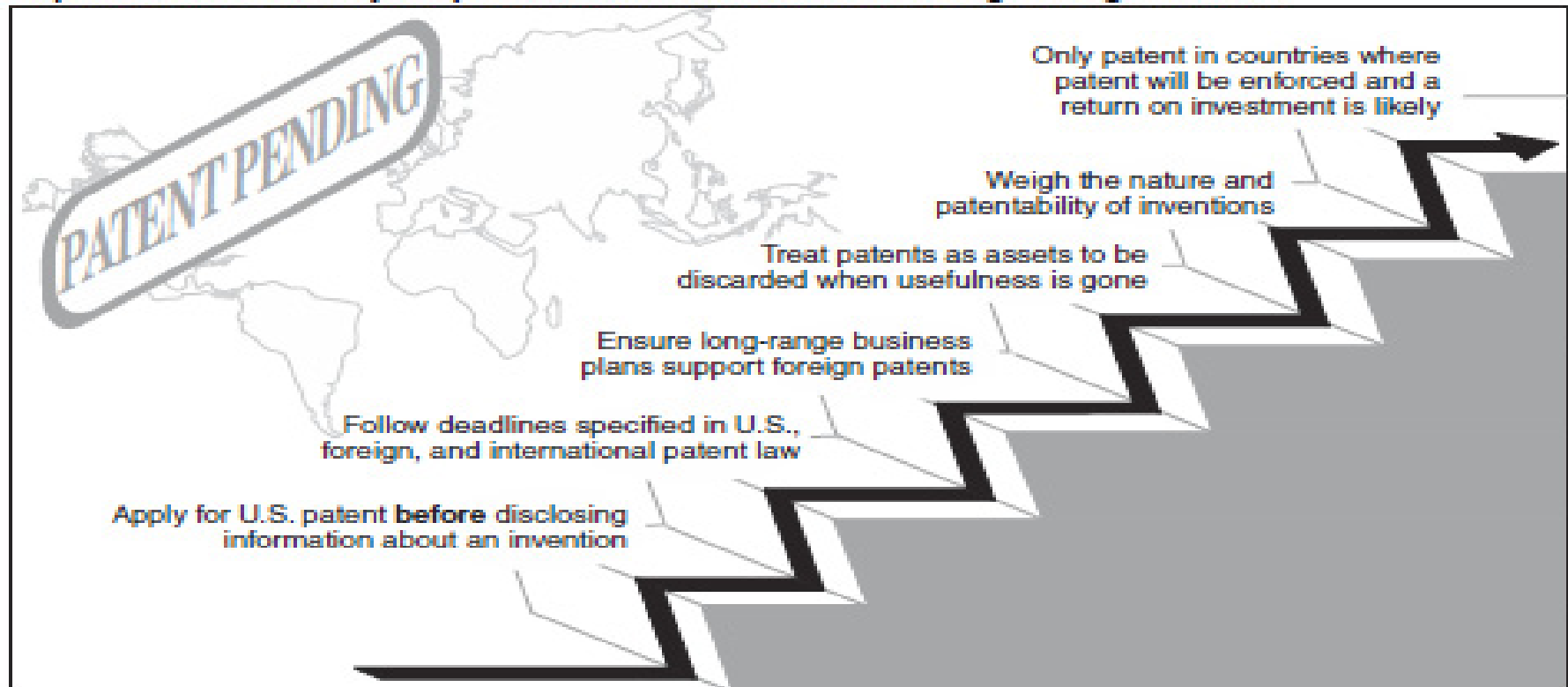
26-28 month window for decision to enter national stage



## Actions

# Key Considerations

## Experts' Views on Key Steps for Small Businesses Seeking Foreign Patents



Source: GAO analysis of patent attorney panel questionnaires.

# Requirements for a U.S. Patent



# Statutory Requirements

## 35 U.S.C.

- § 101 (Subject matter/Utility)
- § 102 (Novelty)
- § 103 (Non-Obviousness)
- § 112 (Textual Requirements)

# § 101 Eligible Subject Matter

- Process
- Machine
- Article of Manufacture
- Composition of Matter, or
- An Improvement Thereof

“Anything under the sun that is made by man.”

– *Diamond v. Chakrabarty*, 447 U.S. 303

# § 101 Utility

- An invention must be "useful".
- The utility must be specific, substantial, and credible and not:
  - illegal,
  - immoral or
  - contrary to public policy.

# § 102 Summarized

- The invention:
  - was not known or used by others,
  - was not patented or described in a printed publication anywhere, either domestic or foreign,
  - was not offered for sale/license more than one year before application filing,
  - was not described in another's earlier published patent application or patent,
  - was not made by another who did not abandon, suppress, or conceal.

## § 103 Nonobviousness

A patent may not be obtained though the invention is not identically disclosed...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been *obvious* at the time the invention was made to a person having *ordinary skill* in the art to which said subject matter pertains.



# Obviousness Factual Inquiries

- Basic Factual Inquires:
  - the scope and content of the prior art,
  - the differences between the prior art and the claims at issues, and
  - the level of ordinary skill in the pertinent art.
  
- Secondary Considerations:
  - unexpected results
  - the long felt need or failure of others
  - commercial success.

# § 112 Summarized

- First paragraph:
  - written description
  - enablement
  - best mode
  
- Second paragraph:
  - indefiniteness
  - what the inventor regards as the invention.

# Written Description

- “A patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.”
- “An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.”

**U.S.P.T.O., 2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. - 2100 Patentability**

# Enablement

- Whether the person of skill in the art can practice the invention without undue experimentation.
- The test for compliance with §112 is not whether experimentation is necessary, but whether any experimentation would be undue in view of what type and amount of experimentation are usual in the field.

# Enablement

- Factors for consideration:
  - quantity of experimentation,
  - amount of direction in the application,
  - presence or absence of working examples,
  - nature of the invention,
  - state of the prior art,
  - level of skill in the art,
  - predictability or unpredictability in the art, and
  - breadth of the claim.

# Best Mode

- Prevents concealment by a patent applicant of special techniques or devices.
- It requires the best mode contemplated *at the time of filing* the patent application.

# Recent Cases Impacting Personalized Medicine



## *In re Bilski* (Fed.Cir. 2008)

- Methods of hedging risk when trading commodities
- Impact of upcoming SCT decision?



# *In re Bilski*

- “Machine or transformation” test for patent eligibility under §101.
  
- Invention meets requirements if:
  - (1) it is tied to a particular machine or apparatus, or
  - (2) it transforms a particular article into a different state or thing.

## *In re Bilski*

- The claimed “use of a specific machine or transformation of an article must impose meaningful limits on the claim’s scope”
- The machine or transformation must not consist merely of “insignificant extra-solution activity”
- The “transformation must be central to the purpose of the claimed process”
- In most cases, merely “gathering data would not constitute a transformation of any article”

# *Prometheus Labs. v. Mayo Collaborative Services* (Fed.Cir. 2009)

- Applied Bilski's "machine or transformation" test to the medical arts.
- Confirmed that methods for determining the level of a metabolite in a patient sample and using it to select a treatment option are patent eligible.

# *Prometheus* cont'd

## Exemplary Claim

- A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
  - (a) administering a drug providing 6-thioguanine to a subject ...; and
  - (b) determining a level of 6-thioguanine or 6-methyl-mercaptopurine ... ,

[wherein certain levels indicate the need to increase or decrease the amount of the drug in subsequent administrations]

# *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.* (Fed.Cir. 2009)

- *Vacated and re-hearing en banc granted*
- Future of written description?

## *Ariad* cont'd: Exemplary Claim

[A method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF-KB-mediated intracellular signaling, the method comprising altering NF-KB activity in the cells such that NF-KB-mediated effects of external influences are modified, wherein NF-KB activity in the cell is reduced] wherein reducing NF-KB activity comprises reducing binding of NF-KB to NF-KB recognition sites on genes which are transcriptionally regulated by NF-KB.

## *In re Alonso* (Fed.Cir. 2008)

- Single mAb example was insufficient to show possession of the broad genus of antibodies claimed.

## *Alonso* cont'd: Exemplary Claim

A method of treating neurofibrosarcoma in a human by administering an effective amount of a mono-clonal antibody idiotypic to the neurofibrosarcoma of said human, wherein said monoclonal antibody is secreted from a human-human hybridoma de-rived from the neurofibrosarcoma cells.



## *Ex parte Kubin* (BPAI 2007)

- “Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features.”

## *Ex parte Kubin* Cont'd: Exemplary Claim

An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48.

## *In re Kubin* (Fed.Cir. 2009)

- Acknowledged the Supreme Court's apparent overruling of the landmark biotech case *In re Duel*.
- Held that elucidating the nucleic acid sequences of known proteins has become routine and predictable.

# Practice Tips

- Give due consideration to “transformation” steps
- For diagnostic claims: theranostic vs. data gathering
- Consider pursuing nucleic acid claims only when the corresponding protein is novel
- Identify a number of exemplary “species”
- Prioritize working examples
- Identify critical portion of protein’s structure
- Identify critical portion/length of nucleic acid

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